

REMARKS

Claims 1-10 are all the claims pending in the application. Claims 1 and 9 have been amended to more clearly point out what inventors consider their invention. Support for the amendment to claims 1 and 9 can be found at, for example, original claim 11 and the specification, page 7, lines 10-16. Claim 11 has been canceled. No new matter has been introduced and entry of the amendment is respectfully requested.

Claims 1-10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 2002/0032171, “Chen”); and claims 1-7 and 9-11 under 35 U.S.C. 103(a), over Lambert et al. (US 6,458,373), against the applicant’s argument filed on February 12, 2007. However, in view of the above amendments made to claims and for the reasons provided below, early allowance of pending claims 1-10 is respectfully requested.

First, the Examiner’s kind attention is invited to the fact that both claims 1 and 9 have been amended so as that the inherent characteristics of the microemulsion concentrate prepared by the inventive method are clearly represented by incorporating therein the disclosures of claim 11 and lines 10-16, page 7 of the specification as originally filed.

The above-mentioned characteristics of the inventive microemulsion concentrate results from the critical feature of the inventive method, which comprises first dissolving the “water-insoluble anti-cold drug” in the co-surfactant such as “ethanol” to obtain a homogeneous drug solution and then adding the “surfactant” and “oil” thereto, followed by removal of the co-surfactant therefrom.

Specifically, when the water-insoluble anti-cold drug alone is dissolved in the co-surfactant having high solubility thereof, the drug solution thus obtained includes the drug in a very stable state. Subsequently, the addition of two components, the surfactant and oil, to the drug solution generates a microemulsion concentrate containing very stable emulsified drug microparticles after the removal of the co-surfactant. The emulsified drug microparticles contained in the inventive microemulsion concentrate are so stable toward the pH change that the emulsified state resists any precipitation of the drug. The inventive microemulsion concentrate easily forms microparticles having an average particle size ranging from 270 to 500nm upon contact with an aqueous solution. Accordingly, the inventive microemulsion concentrate can provide an improved bioavailability of the drug when orally administered, which is little influenced by pH change (see lines 7-17, page 7 of the present specification). Such beneficial effects of the present invention are fully supported by Test Examples 1 (dissolution test), 2 (analysis of the emulsified drug microparticles), 3 (precipitation formation test) and 4 (absorption test) of the specification as originally filed.

In spite of the Examiner's indication that the selection of any order of mixing ingredients is obvious, the inventive technical feature (i.e., mixing of specific components in a specific order prior to the removal of the co-surfactant) as well as the aforementioned beneficial effects arising therefrom are not taught, suggested or implied by the Chen and Lambert, even if they are combined.

Further, as the Examiner has pointed out, in the method disclosed in lines 6-18, col. 4 of the Lambert patent, the "surfactant" is added to an ethanol-free tocopherol and therapeutic agent

solution obtained after the removal of ethanol, and accordingly, it is also different from the method of the present invention.

Thus, the present invention defined in pending claims 1-10 is clearly patentable and unobvious over the cited references, and it is respectfully submitted that the 103 rejections of claims 1-10 be withdrawn.

Meanwhile, the Examiner has indicated that the comparative study in the Inventor's declaration filed together with the previous response is unclear in connection with the mixing order of components.

In this regard, please note that in Example 1 of the present invention, ibuprofen was uniformly dissolved in ethanol, and then polyoxyethylene-40-hydrogenated castor oil, Fluronic® L-44NF, Tween® 20 and propyleneglycol monocaprylate were added to the ibuprofen solution in order and dissolved; while in a series of comparative experiments, polyoxyethylene-40-hydrogenated castor oil, Fluronic® L-44NF, Tween® 20, propyleneglycol monocaprylate and ibuprofen were added to ethanol in order, and all of them were dissolved. Enclosed herewith please find a Supplemental Declaration in which such a specific mixing order of components is incorporated.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

AMENDMENT UNDER 37 C.F.R. § 1.116
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The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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